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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/587,535
Filing Date: April 05, 2007
Appellant(s): CARROLL ET AL.

Pamela J. Sherwood
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4 November 2008 appealing from the Office action mailed 24 June 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2001/0023243	Donovan	9-2001
2001/0056275	Brushey	12-2001

Kim 2002 Autonomic Neuroscience 102:8-12

Erickson 1993 Radiology 188:707-709

Henrard 1982 Arch Mal Coeur 75(11):1317-1320, including English language abstract on p. 1320.

Purves 2001 Neuroscience 2nd Edition, Chapter 21, Box B.

Onal 1999 General Pharmacology 33:83 – 89.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

I. Claims 1 – 3 and 5 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim 2002 (Autonomic Neuroscience 102:8-12) in view of Donovan (U.S. Patent Application Publication 2001/0023243).

Kim teaches sympathetically mediated chronic pain is mediated by the sympathetic ganglion (see p. 8 first paragraph). While Kim did not treat human patients with sympathetic pain, the authors present the results of experiments indicating that botulinum toxin, when administered to the superior cervical ganglion, can inactivate the nerves in that ganglion and prevent them from having their effects. Type A toxin, recited in claims 1 – 2, was used by the authors in their experiments (see p. 9, section entitled “Surgical Procedure”). The dose used was 2 - 10 units per kilogram of body weight (p. 9, “Experimental animals”), administered to rabbits which is within the range recited in claim 3, given that rabbits weigh less than 30 kg. The reference teaches administration to the superior cervical ganglion as recited in claim 5 - 6. The data presented by Kim show that the toxin induces miosis, which is the constriction of the pupil within the eye. According to Kim, this indicates that botulinum toxin acts on the sympathetic neurons of the superior cervical ganglion (p. 11, second paragraph). Kim concludes that the histological findings were normal, indicating that botulinum toxin "may be used clinically as a safe neurolytic agent" (p. 11, paragraph spanning the two columns) and that the results indicate that the toxin is likely to be useful in treating sympathetically mediated pain, as recited in claim 1 (p. 11, final paragraph). However Kim does not teach administration to humans, and does not explicitly teach percutaneous injection as recited in claim 1. Rather Kim teaches administration rabbits and teaches direct administration to the ganglion following surgical opening of the skin and underlying tissues.

Donovan teaches that botulinum toxin A, recited in claims 1 and 2, can be administered to a human patient via percutaneous injection in order to achieve a block of nerves within the sympathetic ganglia. See for example paragraph [0090], which details that a percutaneous injection can be used, and paragraph [0092], which indicates that sympathetic ganglia can be

targeted, that type A toxin should be used, and that human patients should be treated. Donovan also teaches that inactivating nerves within the celiac plexus is known to treat pain and that the methods known to block the celiac plexus can also be used to block sympathetic ganglia (paragraph [0090]). Donovan teaches that performing the methods of his invention, which include administration of botulinum toxin A to human patients by percutaneous injection to sympathetic ganglia, reduce pain (paragraph [0091]). However, Donovan does not explicitly teach that the method is useful for treating sympathetically mediated chronic pain, as recited in claim 1.

It would have been obvious to one of ordinary skill in the art to modify the method of Kim, who teaches administration of botulinum toxin A to the superior cervical ganglion is sufficient to inactive nerves within that ganglion, by following the guidance of Donovan, who teaches that in order to inactivate nerves within a sympathetic ganglion one should administer botulinum toxin A to human patients via percutaneous injection, thereby arriving at the invention of claims 1 – 3 and 5 – 6. Kim suggests that botulinum toxin A will be useful as treatment for sympathetically mediated pain, and Donovan states that the same toxin is known to be effective in treating pain.

II. Claims 1 – 3 and 5 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Donovan as applied to claims 1 – 3 and 5 – 6 above, and further in view of Erickson 1993 (Radiology 188:707-709).

The reasons why claims 1 – 3 and 5 – 6 are obvious over Kim in view of Donovan are set forth above. However, neither of these references teaches administering a local anesthetic as a sympathetic block and identifying chronic pain as being mediated by the sympathetic nervous system as recited in claim 7.

Erickson teaches methods of administering local anesthetics, including lidocaine, bupivarcaine, and buprenophrine as sympathetic blocks. The specific drugs are listed in the abstract, and the first paragraph of the Materials and Methods section teaches that the stellate ganglion, which is a sympathetic ganglion, was the target. Erickson teaches the method is successful in human patients, as recited in claim 1, and leads to pain relief, including complete pain relief which is more than 50% of the perceived pain as recited in claim 7 (see results section). Erickson teaches that the duration of relief is generally short, between one hour and

three weeks. However Erickson does not teach administration of botulinum toxin as recited in claim 1.

It would have been obvious to one of ordinary skill in the art to include the step of administering a short-acting local anesthetic as a sympathetic block, as taught by Erickson, when performing the methods of claims 1 – 3 and 5 – 6, which are rendered obvious by Kim and Donovan, thereby arriving at the invention of claim 7. The motivation to do so would be to ensure that the pain experienced by the patient is in fact mediated by the sympathetic ganglia. Performing this step would be advantageous, as it would ensure that those patients whose pain is not mediated by sympathetic ganglia will not be exposed to the toxin. Thus by performing the step taught by Erickson and recited in claim 7, the artisan would ensure identification of the patients most amenable to treatment.

III. Claims 1 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Donovan as applied to claims 1 – 3 and 5 – 6 above, and further in view of Brushey (U.S. Patent Application Publication 2001/0056275).

The reasons why claims 1 – 3 and 5 – 6 are obvious over Kim in view of Donovan are set forth above. However, neither of these references teaches administration to a sympathetic ganglion and achieving a block of the splanchnic nerve when pain is in the lower extremities, as recited in claim 4.

Brushey discusses administration of anesthetics in order to decrease pain and teaches that when sympathetic pain is present in the lower extremities, the splanchnic nerve should be blocked (see paragraphs 0004 - 0005). However Brushey does not teach administration of botulinum toxin as recited in claim 1.

It would have been obvious to one of ordinary skill in the art to modify the methods rendered obvious by Kim and Donovan such that when the pain is present in the lower extremities, the toxin would be given to block the splanchnic nerve. The motivation to do so would be to effectively block pain, as Brushey teaches this is the nerve to be blocked when pain is present in the lower extremity, thereby guiding the artisan of ordinary skill to select this particular anatomic locus for treating this particular type of pain.

IV. Claims 1 – 3, 5 – 6, 8 – 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henrard 1982 (Arch Mal Coeur 75(11):1317-1320) in view of Kim and Donovan.

Henrard teaches treatment of coronary vasospasm which is on point to claims 8 – 9. This is a form of peripheral vascular disease, which is recited in both claims 8 – 9. Note that vasospasms are defined by applicant to be vascular diseases suitable for treatment with the invention (specification, p. 12 paragraph [61]). Henrard teaches that the spasms can be treated by homolateral thoracic sympathectomy, i.e. surgical removal of a sympathetic ganglion (see abstract translation on p. 1320). However Henrard does not teach administration of boutlinum toxin.

The reasons why claims 1 – 3 and 5 – 6 are obvious over Kim in view of Donovan are set forth above in section I and for the sake of brevity are not reiterated here. Note that the references provide guidance to select botulinum toxin A, the specific doses recited in the claims, human patients, and relief from pain as detailed in **I** above. Kim teaches pain relief by administering botulinum toxin to a sympathetic ganglion, which is on point to claims 8 and 10, and the doses as recited in claim 12. However, Kim does not teach administering botulinum toxin to patients with cardiovascular conditions as recited in claims 8 – 9.

Donovan teaches administration of botulinum toxin to sympathetic ganglia by percutaneous injection, but does not explicitly teach using this method to treat patients with the diseases recited in claims 8 – 9.

It would have been obvious to one of ordinary skill in the art to modify the method of Henrard by administering botulinum toxin to the sympathetic ganglion instead of removing the sympathetic ganglion, thereby arriving at the invention of claims 8 – 10 and 12. Henrard teaches that inactivating the ganglion by removal is sufficient for treatment of spasm, and using botulinum toxin for inactivation, as taught by Kim, would be advantageous as it would be less invasive. Additionally, selection of the method of administration taught by Donovan, namely percutaneous injection, would be advantageous as it would allow for the toxin to penetrate and inactivate the ganglia without requiring surgery. Note claim 10 is included in this rejection as it does not recite any additional starting materials or steps, but rather recites effects which will happen upon administration.

(10) Response to Argument

Each of the rejections listed as I – IV above is argued separately by appellant, and the arguments will be addressed in turn.

I. Appellant makes the following arguments against the examiner's determination that the invention of claims 1 – 3 and 5 – 6 would have been obvious to one of ordinary skill in the art upon reading Kim and Donovan. Specifically, appellant argues:

A. The reference by Kim does not teach a block of the neurons, but rather killing them, as evidenced by Kim's use of the word "neurolytic" and a dictionary definition of that term provided by appellant.

B. Kim's teachings are limited to miosis and do not speak to utility for botulinum toxin for treating pain.

C. There is a lack of correlation between pupil dilation, measured by Kim, and pain relief, encompassed by the claims, so the findings of Kim cannot be extended to pain relief.

D. Even if such a correlation existed, the results in rabbits could not be extended to humans.

E. The teachings of Donovan on the efficacy of agents other than botulinum toxin in treating pain do not guide the artisan of ordinary skill to select this toxin for treating pain.

F. While Donovan teaches that certain other conditions can be treated by percutaneous administration of botulinum toxin, those teachings fail to guide the artisan of ordinary skill to treating sympathetic pain by the same method.

With respect to A, the examiner disagrees with appellant's conclusion that the term "neurolytic" is to be construed as defined by The American Heritage Dictionary, particularly an edition published in 2004 and revised in 2007, i.e. two to five years after the reference by Kim was published. Kim does in fact use the term "neurolytic" when discussing botulinum toxin A (BTA). However, Kim is aware that BTA does not kill neurons. On p. 8 final paragraph, Kim teaches that BTA inhibits secretion of acetylcholine from neurons, and cites a 1981 paper that explains this in more detail. Additionally, Kim contrasts BTA with "conventional neurolytic agents such as alcohol and phenol compounds" which "are known to destroy nerve fibers non-selectively and permanently" (p. 11 fourth paragraph). Kim discusses the histological findings of the experiments, which indicate that BTA does not damage the tissue into which it is

administered. Clearly, Kim was aware that BTA does not kill neurons, and even presents evidence that the toxin does not damage tissue. Kim clearly concluded that BTA is able to block neurons, even though the term "neurolytic" is used; see p. 11 final paragraph which states that "... the main finding of our study is that BTA has a sympathetic ganglion blocking effect of more than one month, without inducing considerable pathologic changes in the SCG." Thus the argument that Kim failed to realize that BTA is a nerve-blocking agent as opposed to a nerve-killing agent is unpersuasive.

With respect to B, the examiner disagrees with appellant's argument that Kim's teachings are limited to miosis and do not speak to treating pain. First, it is important to note that Kim specifically discusses blocking sympathetic ganglia in order to treat chronic pain. Kim discusses previously known treatments for chronic pain, including using alcohol and phenol compounds administered to the ganglia (p. 8 first paragraph). Kim hypothesized that since BTA blocks acetylcholine release (p. 8 second paragraph), and acetylcholine is known to be one of the neurotransmitters released by the sympathetic ganglia, BTA may be effective in decreasing sympathetic activity. In order to test this hypothesis, Kim performed the miosis experiments on rabbits. While Kim did not specifically measure pain or nociception, Kim relies on the well-known connection between miosis and sympathetic neuron activity (see Purves 2001 Neuroscience 2nd Edition, Chapter 21, Box B, cited by the examiner in the Final Rejection mailed 24 June 2008) to conclude that the observed miosis is indicative of a block of sympathetic neurons. Kim also relied on the well-known fact that inactivating sympathetic neurons is an effective way to treat chronic pain (see Kim p. 8 first paragraph, p. 11 first column final paragraph). From this, Kim concludes that BTA should be used to treat pain that is maintained by sympathetic ganglia (p. 11 final paragraph). Clearly Kim intended the findings of the miosis experiments to be extended to treatment of pain. At the time the invention was made, using BTA to treat this particular form of pain would have been obvious to one of ordinary skill in the art, given that BTA was well-know to treat several types of pain. See Delgado 2003 J. Am. Acad. Orthop Surg. 11(5):291-294, cited by applicant at p. 4 paragraph [18] of the specification as a review of the known medical uses of the toxin and listed as reference 1 on the information disclosure statement filed 24 June 2008. In particular see paragraph spanning pp. 292 - 293 which discloses that botulinum toxin A alleviates several forms of pain including postoperative pain, muscle pain from spasticity, and chronic lower back pain. Additionally Donovan indicates that BTA can be used to treat pain; see for example paragraphs [0090] –

[0091] Given that the prior art, including both the references by Kim and Donovan as well as that referred to by appellant in the specification (Delgado) all speak to the utility of BTA for treating pain, the argument that the findings of Kim should be limited to the subject of miosis is not persuasive. To the contrary, Kim's conclusion that the findings should be extended to treatment of pain are supported by the art at the time the invention was made.

With respect to C, appellant argues that there is not a reliable correlation between the degree of miosis and pain relief (or analgesia), so the findings of Kim which measure the former cannot be extended to the latter. Appellant refers to an article by Onal 1999, and states that the article indicates that analgesia is not correlated with pupil response. The examiner has closely reviewed the article and disagrees with appellant's characterization of the data and conclusions. Onal refers to a series of papers published between 1983 and 1993 indicating that opiates are known to modulate both pain sensation and pupil diameter (p. 83, second paragraph). The reference details the results of experiments in which several drugs were administered to animals and both analgesia and changes in pupil diameter were mentioned. Importantly, Onal indicates that those drugs which induce changes in pupil diameter also induce analgesia; see for example Figures 1 - 3. While one drug tested (sertraline) induced analgesia without inducing a change in pupil diameter (see Figure 4) the data are consistent with the conclusion offered by Kim, namely that inducing a change in pupil diameter is indicative of a change in pain thereshold. Importantly Onal indicates that morphine, the most effective analgesic tested, induces a strong change in pupil diameter (Figures 1 – 2), and that opiates (the class of drugs to which morphine belongs) affect the sympathetic nervous system, which leads to changes in pupil diameter (p. 83 second paragraph). Thus the data presented by Onal, combined with the plethora of references cited by the authors, indicate that at the time the invention was made a change in pupil diameter was generally regarded as indicative of a change in pain threshold. Therefore, Kim properly concluded that the observed changes in pupil diameter induced by BTA were indicative of its efficacy in modulating sympathetically mediated chronic pain. Accordingly, one of ordinary skill in the art would have found it obvious to follow the guidance set forth by Kim, who suggests that BTA will be useful as a treatment for sympathetically mediated chronic pain (p. 11 final paragraph).

With respect to D, appellant argues that one of ordinary skill in the art would not have found it obvious to extend the findings of Kim to humans. Appellant cites a reference by Campbell and Meyer, published after the present invention was made, as providing support for

the argument that the findings in rabbits should not be extended to humans. Beyond appellant's quotation of a single paragraph from this reference, no copy of the paper has been made of record. The reference was not submitted with the response after the non-final office action, and was not cited on an information disclosure statement. Thus the examiner is unable to evaluate the reference beyond the paragraph quoted by appellant. Nevertheless, the single quoted paragraph does not indicate that there is no predictive value in the art-accepted animal models of analgesia, such as those used by Onal. The quoted paragraph indicates that some researchers have hypothesized different mechanisms for some of the results observed in analgesia studies, however the existence of other explanations of observed analgesic effects of drugs does not negate the predictive value of analgesic experiments, such as those referred to and performed by Onal. In general, the evidence of record indicates that experiments on both analgesia and block of the sympathetic nervous system are predictive of success in humans.

With respect to E, appellant argues that while Donovan acknowledges that other compounds were known to be effective in treating sympathetically mediated pain, the reference fails to teach or guide the artisan of ordinary skill to select BTA for treating this disorder. This argument is not persuasive. At paragraph [0090], Donovan states that "it is know to inject the celiac plexus with ethanol or phenol to provide relief from the pain which can result from pancreatic cancer". In the same paragraph, Donovan teaches the artisan of ordinary skill that "[c]ervical ganglion block according to the present invention can be carried out in the same manner as a celiac plexus block." This indicates to the artisan of ordinary skill that the methods known to be effective in blocking the celiac plexus can also be used to block sympathetic ganglia, and vice versa. Finally, in the very next paragraph, Donovan indicates that "a surprisingly effective and long lasting therapeutic effect can be achieve by local administration of a neurotoxin…to a sympathetic ganglion." Later in that paragraph Donovan indicates that "[i]n its most preferred embodiment, the present invention is practiced by direction injection into a parathyroid gland, or into a sympathetic ganglion… a therapeutically effective amount of botulinum toxin, such as botulinum toxin type A." While the reference does not explicitly teach that chronic sympathetically mediated pain is to be treated by this toxin, given that Donovan teaches both i) that BTA when administered to a sympathetic ganglion can block the ganglion and ii) blocking a sympathetic ganglion with other agents such as alcohol or phenol can treat pain, the artisan of ordinary skill would have found it obvious to use BTA rather than phenol in blocking pain. Note in particular MPEP 2144.06(II), which explains that substituting equivalents

known to be effective for the same purpose is prima facie obvious. Coupled with the teachings of Kim, who indicate the superior nature of BTA due to its lack of damaging effects on tissue as compared with alcohol, the artisan of ordinary skill would have found it obvious to use BTA to treat chronic sympathetically mediated pain.

With respect to F, appellant argues that although Donovan teaches different conditions such as parathyroid disorders can be treated by percutaneous administration of BTA, the reference fails to indicate that chronic sympathetically mediated pain is to be treated in this manner. The examiner respectfully disagrees with appellant's conclusion. As explained in the preceding paragraph, since Donovan indicates the well-known therapeutic efficacy of inactivating sympathetic ganglia by percutaneous injection in treating sympathetically mediated pain, and indicates that BTA can inactivate sympathetic ganglia, it would have been obvious to one of ordinary skill in the art to select this toxin and this route of administration. At paragraph [0090] Donovan indicates to the artisan of ordinary skill that percutaneous injection can be carried out in the absence of surgery. Thus this route of administration of BTA would be advantageous, as compared to the surgical intervention used by Kim, in that it would be less disruptive for the patient.

For the reasons above, the rejection of claims 1 – 3 and 5 – 6 as obvious over Kim in view of Donovan should be maintained.

II. Appellant makes the following arguments against the examiner's determination that the invention of claims 1 – 3 and 5 – 7 would have been obvious to one of ordinary skill in the art upon reading Kim, Donovan, and Erickson. Specifically, appellant argues that the reference by Erickson, who teaches administration of the sodium channel blockers bupivacaine and lidocaine, fails to render obvious the methods of treating chronic sympathetically mediated pain by percutaneous administration of BTA. That is, appellant argues that Erickson fails to cure any deficiencies of Kim and Donovan with respect to claim 1. For the reasons explained in detail above, the references by Kim and Donovan render obvious every feature of the invention defined by claims 1 – 3 and 5 – 6. The specific limitations of claim 7 are taught and rendered obvious by Erickson. Appellant did not traverse the examiner's determination that Erickson teaches every limitation of claim 7, and in fact admitted that the limitations recited in this claim were known at the time the invention was made. At p. 9 of the Brief, appellant concedes that "the use of a local anesthetic to achieve a temporary block is known in the art, as evidenced by

Erickson". As Erickson renders obvious the features of claim 7, the rejection should be maintained.

III. Appellant makes the following arguments against the examiner's determination that the invention of claims 1 – 6 would have been obvious to one of ordinary skill in the art upon reading Kim, Donovan, and Brushey. Specifically, appellant argues that the reference by Brushey, who teaches that when sympathetic pain is present in the lower extremities, the splanchnic nerve should be blocked, fails to render obvious the methods of treating chronic sympathetically mediated pain by percutaneous administration of BTA. That is, appellant argues that Brushey fails to cure any deficiencies of Kim and Donovan with respect to claim 1. For the reasons explained in detail above, the references by Kim and Donovan render obvious every feature of the invention defined by claims 1 – 3 and 5 – 6. Appellant did not traverse the examiner's determination that Brushey both teaches and renders obvious the limitations of claim 4 that are not present in claim 1, namely administering to a sympathetic ganglion and blocking the lumbar splanchic nerves in order to treat pain of the lower extremities. As Brushey renders obvious the particular limitations of claim 4, this rejection should be maintained.

IV. Appellant makes the following arguments against the examiner's determination that the invention of claims 1 – 3, 5 – 6, 8 - 10, and 12 would have been obvious to one of ordinary skill in the art upon reading Henrard, Kim, and Donovan.

According to appellant, since Henrard used a surgical method to remove the sympathetic ganglia, this gross procedure does not guide the artisan of ordinary skill to administer the selective BTA. According to appellant, Kim fails to cure the deficiency of Henrard, as Kim does not teach that BTA can be used to treat the same diseases that Henrard treated by surgical removal of the ganglion. Additionally, appellant argues that Donovan fails to cure the deficiency of Henrard, as Donovan does not teach that BTA can be used to treat the same diseases that Henrard treated by surgical removal of the ganglion, although appellants admit that Donovan does teach percutaneous injection.

The examiner concedes that Henrard does not teach administration of the neurotoxin BTA to treat coronary vasospasm, which is a disease within the scope of claims 8 – 9. Rather Henrard used surgery to completely remove the thoracic sympathetic ganglia. The authors report that this treatment led to remission of the spasms in both patients, although the remission

was only short-term in one of the patients. In order to treat the patient whose vasospasm had returned, Henrard had to undertake a more complete removal of nerves, specifically a "complete denervation by plexectomy" (English abstract, p. 1320). This second surgery led to the death of the patient two hours after the operation. Owing to the fact that the second surgery resulted in death, the artisan of ordinary skill would have motivated to find a procedure that is less invasive but nonetheless still effective in blocking the activity of the neurons within the sympathetic ganglia. Thus the artisan of ordinary skill would have looked for other treatments known to be effective in blocking sympathetic activity.

Kim teaches that BTA inactivates the sympathetic ganglia in vivo. See for example p. 11 first column, where the authors conclude "this is the first demonstration that BTA has blocking effects on the sympathetic ganglion in vivo." While Kim does not teach the specific route of administration recited in claims 8 – 9, Donovan in fact teaches that BTA can be administered by percutaneous injection in order to inactivate sympathetic ganglia. Because no surgery is required (see Donovan paragraph [0090]), the complications observed by Henrard, specifically death of one of the patients soon after surgery, would likely be avoided. Given that Kim teaches that BTA is effective in stopping activity of the sympathetic ganglia, which of course is the result achieved by the surgical removal of these cells by Henrard, the artisan of ordinary skill would have had a reasonable expectation of success in administering BTA to treat these diseases. The motivation to use a relatively non-invasive method (i.e., percutaneous injection as taught by Donovan) comes directly from the references themselves, as Henrard teaches the unfortunate risks of surgery, and Donovan indicates that the percutaneous injection can eliminate the need for surgery. Therefore, the rejection of claims 8 – 10 and 12 as obvious over Henrard in view of Kim and Donovan should be maintained. Claims 1 - 3 and 5 - 6 are obvious over Kim in view of Donovan as explained in **I** above and therefore are included in this rejection. For the sake of brevity, the reasons why these two references render obvious claims 1 - 3 and 5 -6 will not be repeated herein.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Daniel E. Kolker/

Primary Examiner, Art Unit 1649

Conferees:

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649

/Dave Nguyen/

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